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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/768,020	01/23/2001	Ralph J. Greenspan	066655-0026	9299

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EXAMINER	
SCHULTZ, JAMES	
ART UNIT	PAPER NUMBER
1633	

NOTIFICATION DATE	DELIVERY MODE
03/22/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

SIP_Docket@mwe.com

Office Action Summary	Application No.	Applicant(s)	
	09/768,020	GREENSPAN ET AL.	
	Examiner	Art Unit	
	JD SCHULTZ	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12/28/2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *22,23 and 27-29* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *22,23 and 27-29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Application/Amendment/Claims

Please note that the examination of this application has been transferred to a different examiner, whose contact information can be viewed at the end of this action.

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on December 28, 2009 has been entered. Claims 22, 23, and 27-29, filed12/28/2009, are pending. Claims 22, 23, and 27-29 are the subject of the present Official action.

Any rejection or objection not repeated herein is hereby withdrawn.

Claim Rejections - 35 USC § 112

These rejections are repeated for reasons of record as set forth June 28, 2007.

Claims 22, 23, and 27-29 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 22, 23, and 27-29 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not

described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

At the outset it is noted that the rejections for written description and enablement are separate; however, since both rejections are fundamentally premised upon the finding of unpredictability as discussed below, the rejections for the purpose of discussion are combined.

The claims are drawn to methods of identifying therapeutic agents for treating Alzheimer's disease, comprising performing matings between a first parent strain carrying a mutation in Alzheimer's disease gene selected from a select group of genes and a second parent strain containing a genetic variation whereby test progeny are produced such that test progeny possess altered phenotypes relative to their siblings, and administering an agent to at least the first parent strain, the second parent strain, or said test progeny, and assaying for altered phenotypes in the test progeny which thereby indicates the compound is a test compound.

Consideration #1: The select group of genes listed in independent claim 22 comprise numerous genes which are apparently specific to Drosophila, such as halothane resistant, (har38), Suppressor of Hairless (SUH), mastermind (mam), and big brain (bb), as well as some that are known to be involved in Alzheimer's pathogenesis such as presenilin.

Consideration #2: Independent claim 22 defines the successful discovery of a therapeutic agent for Alzheimer's disease as simply identifying a compound that modifies the phenotype of the test progeny relative to one of its siblings.

Consideration #3: The specification contemplates numerous hosts capable of having the screen performed in, but exemplifies only in Drosophila.

Consideration #3: Alzheimer's disease is a human disease. While the prior art may cite numerous animal models, there is considerable debate as to how closely such models represent a disease of the human brain, particularly since the disease typically manifests first in the form of dementia and memory loss, phenomena which are hard to measure in non-humans. There are those in the art who believe that Alzheimer's cannot be truly diagnosed until the time of autopsy.

Consideration #4: A brief review of the literature reveals total silence in the prior art regarding any such connection between Drosophila specific genes such as those listed above, and Alzheimer's disease, which is considered to be a human disease.

Consideration #5: The specification discloses numerous genes that associated directly or indirectly with a Drosophila analog of amyloid precursor protein, said analog termed Appl.

Consideration #6: The specification prophetically contemplates numerous genetic systems (i.e. mice, zebra fish, yeast, etc.) allegedly suitable for practicing the methods of the invention.

Consideration #7: the specification prophetically contemplates numerous altered phenotypes that may be indicative of the disease state, including size, viability, eye color, coat color, or exploratory behavior etc.

It is submitted that the unpredictability evident from the prior art towards developing successful Alzheimer's disease treatments, which clearly have proven elusive, taken together with the claim language which recites numerous genes with no established connection to Alzheimer's disease, create a gap that prevents the successful practice of the instant invention, a gap not filled by either the specification or the prior art. As applicants correctly indicate, the

specification provides a listing of genes, organisms, and phenotypes that may be tested. That is not in dispute. Using this, the specification is considered to provide a template by which to screen certain organisms for a link between mutations in certain Drosophila genes that associate with a gene that may be related to a target in humans having Alzheimer's and changes in phenotype in those organisms.

However, there is considered to be a significant scientific gap between this disclosure and the successful practice of the claimed method, which requires the discovery of an Alzheimer's therapeutic based upon mere observation of a phenotype change in an organism that by most counts is incapable of having Alzheimer's. The list of genes and organisms provided does not fill this gap, and neither does the listing of possible phenotypes which might be affected upon the administration of a test compound. There simply is not a strong enough cause and effect relationship between assuming that compounds that affect mutations in Drosophila homologs significantly enough to affect a phenotype will necessarily or even probably be an agent that treats Alzheimer's. Accordingly, the unpredictability is high enough that the specification is not considered to support the structure function requirement that the instant claims require to be considered in possession of the invention, or to enable it, since the specification combined with the prior art don't support the connection between mutations in the claimed genes in non-human organisms and their role as predictors of therapeutic agents in treating a human disease.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JD SCHULTZ whose telephone number is (571)272-0763. The examiner can normally be reached on 8:00-4:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on 571-272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/JD SCHULTZ/
Primary Examiner, Art Unit 1633